

**REMARKS/ARGUMENTS**

Claims 2-13, 18-31, 33-39, and 51-54 remain in this application. Claims 42, 43, 45-50 were canceled herein. Claim 53 was amended to clearly define the range to which the transmissivity of the container pertained. Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned **"Version with marking to show changes made."** The amendment to claim 53 was minor, and introduced herein to place that claim in condition for allowance. Claims 42, 43, 45-50 were canceled herein to lessen the issues for appeal. It is therefore respectfully requested that this Amendment After Final be entered into the application, and the application be allowed to issue as a patent.

The Final Office Action rejected the claims under 35 U.S.C. 103(a) as being unpatentable over Clark et al (U.S.P.N. 5,786,598) in view of Matner et al (U.S.P.N. 5,252,484) and further in view of Shalaby et al (U.S.P.N. 5,422,068), Dunn et al (U.S.P.N. 4,910,942), and Heyl et al (U.S.P.N. 5,431,879).

Applicants traverse all the rejections for all the reasons discussed in the prior responses. The amendments to the claims, and cancellation of some of the claims were done herein solely to move the case to allowance or to lessen the issues for appeal.

Applicants' independent claim, claim 51 provides:

51. A process of sterilizing a contact lens within a container comprising the step of:

subjecting said contact lens to ultraviolet radiation in the range of 240 to 280 nm, wherein said contact lens is in a hermetically sealed container, and further wherein said container is transmissive to at least 50 % of said radiation in the range of 240 to 280 nm in substantially all directions. (Emphasis added)

Claim 51 provides a process in which a contact lens within a container is subjected to radiation and the container is transmissive to at least 50 % of said radiation in the range of 240 to 280 nm in substantially all directions.

The Office Action states that Clark et al disclose exposing a contact lens to radiation in substantially all directions, and cites Figure 8 as support.

Regarding this issue, the Office Action states:

*“wherein the contact lens is in a hermetically sealed container (col. 8, line 33), and further the container is transmissive to at least 50% of UV (abstract, lines 3-5, col. 3, lines 53-54, lines 59-63. Thus, such citations include any percentage value for transmissivity. For example, 80% or 50% or the like) in substantially all directions (figure 8);...” (Office Action, page 3)*

Applicants traverse this rejection. Clark et al do not teach nor suggest subjecting a contact lens container to radiation wherein the contact lens container is transmissive to radiation in substantially all the directions.

Clark et al disclose a contact lens container having a foil backing and a container at which radiation is directed only at the blister opposite the foil backing side.

Again, the Office Action referred to Figure 8 to support the statement that Clark et al show treating a contact lens container that is transmissive to radiation in substantially all directions.

Clark et al state: “FIG. 8 is an end view of the parenteral package of FIG. 2 and another variation of the sterilizing chamber (or tunnel) of the apparatus of FIG. 1.” (col. 5, lines 25-27).

Clark et al define the parenteral (and enteral) containers as those that are made of a flexible pouch and two short tubes that are used to deliver liquid from the pouch to a feed tube. (col. 7, lines 20-27 and lines 36-42). Therefore, Figure 8 does not show a contact lens container receiving radiation from substantially all directions.

Clark et al show and describe the treatment of a contact lens in a container in Figures 3, 4, 5, and 6.

Clark et al state:

“Referring to FIG. 3, a top view is shown of a contact lens package 50, having a “hemispherical” blister 52, and being suitable for use in the sterilizing chamber (or tunnel). The contact lens package 50 has a polyolefin panel 54 (such as a polyethylene panel) into which is formed the blister 52. The blister 52 protrudes from a top side 56 (FIG. 4) of the polyolefin panel 56, and a foil backing 58 (FIG. 4) is adhered to the a bottom 60 of the polyolefin panel 54. Between the foil backing 58, and an interior of the blister 52 is formed a cavity 62 that is filled with a preservative fluid, such as saline solution, and a contact lens 67, such as a soft contact lens.” (col. 7, line 61 - col.8, line 5, emphasis added)

Additionally Clark et states:

“High intensity, short-duration pulses of incoherent polychromatic light 66 (FIG. 4) are in practice directed at the top 56 of the polyolefin panel 54, and the side of the blister... The high-intensity, short-duration pulses of incoherent polychromatic light 66 (FIG. 4) penetrate the blister 52, which is substantially transparent to light having wavelengths in the range selected, and impinge upon the preservative fluid and the contact lens 64, contained therein.” (col. 8, lines 6-20).

Clark et al also state:

“Referring to FIG. 4,...Shown are features of the contact lens package 50 of FIG. 3 with the top and the bottom of the package being more clearly identified, and with arrows representing the high-intensity, short-duration pulses of incoherent polychromatic light 66 as they are directed at the blister 52.” (col. 8, lines 38-46)

Clark et al describe Figures 5 and 6 as showing a substantially similar contact lens package as shown in Figures 3 and 4 except that the blister has a rectangular shape. Figures 5 and 6 show that the radiation is directed at the blister of the package, and Figures 6 shows a foil backing 56, same as Figure 4.

Therefore, Clark et al disclose and describe a contact lens package having a bottom foil layer, and a top consisting of a polyolefin panel that has a blister. The radiation is directed only at the top. It is not directed at the bottom, because the foil layer is not transmissive to the radiation.

Applicants claim a process in which a contact lens is subjected to radiation and the container is transmissive to at least 50 % of said radiation in the range of 240 to 280 nm in substantially all directions. Clark et al do not teach nor suggest such a process. No where does Clark et al teach nor suggest modifying the contact lens package to make it transmissive to radiation in substantially all the directions. No where does Clark et al teach or suggest subjecting a contact lens package to radiation that is directed at the contact lens container other than at the top or blister side of the contact lens container. Therefore, Clark et al do not teach nor suggest Applicants claimed invention.

The Office Action further states that Clark et al suggest a contact lens container that is transmissive in substantially all directions, because at col. 7, lines 1-10, it states that olefins, nylon and composite materials may be employed instead of more conventional materials, such as polyvinyl chloride. That description is directed to modifying the materials of the parental and enteral packages. Clark et al state that PVC is a conventional material for

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parenteral or enteral packages (col. 1, lines 22-27). Clark et al do not state at col. 7, lines 1-10, to substitute any materials for a foil layer, which is a conventional material for the cover layer of a contact lens package. Therefore, Clark et al do not teach or suggest modifying a contact lens package to make it transmissive to radiation in substantially all directions. Additionally none of the cited references alone or in combination with Clark et al teach or suggest a contact lens package which is transmissive to radiation in substantially all directions.

For all the reasons herein and for the reasons stated in the previous Amendment and Response, that are incorporated herein by reference, none of the references cited by the Office Action teach nor suggest Applicants' invention. It is therefore respectfully requested that claims 2-13, 18-31, 33-39, and 51-54 be allowed to issue as a patent.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**In the Claims:**

Claims 42, 43, 45-50 were deleted without prejudice.

Claim 53 was amended as follows:

53. (Amended once) The process of claim 52, wherein said  $D_{\text{value}}$  of Bacillus  
stearothermophilus, ATCC 7953, can be determined for a container by dividing  $3.9 \text{ mJ/cm}^2$   
by the transmissivity of said container to ultraviolet radiation in the range of 240 to 280 nm  
[exposed to said radiation source].

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